IMMUNE RESPONSES TO LYME DISEASE INFECTION AND VACCINATION

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RFA AVAILABLE: AI-94-008

P.T. 34; K.W. 0715125, 0710070, 0740075, 0710075

National Institute of Allergy and Infectious Diseases
National Institute of Arthritis, Musculoskeletal and Skin Diseases

Letter of Intent Receipt Date: February 7, 1994
Application Receipt Date: March 18, 1994

THIS IS A NOTICE OF AVAILABILITY OF A REQUEST FOR APPLICATIONS (RFA); IT IS ONLY AN ABSTRACT OF THE RFA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE RFA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION, FROM THE CONTACT LISTED IN "INQUIRIES", BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE RFA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

The National Institute of Allergy and Infectious Diseases (NIAID) invites applications for research on host immune responses to infection by the etiologic agent of Lyme disease, Borrelia burgdorferi, and research on candidate vaccines for Lyme disease. Research focusing on the characterization of host immunoprotective and immunopathologic responses to infection, host-bacterium-vector interactions, and new vaccine approaches and candidates are appropriate subjects for an application.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Immune Responses to Lyme Disease Infection and Vaccination, is related to the priority areas of immunity and infectious diseases. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Domestic and foreign non-profit and for-profit organizations and institutions, State and local governments and their agencies, are eligible to apply. Minorities and women are encouraged to apply. Foreign institutions are not eligible for First Independent Research Support and Transition (FIRST) (R29) award. Applications from or involving minority institutions or women's institutions are encouraged.

MECHANISMS OF SUPPORT

This RFA will use the National Institutes of Health (NIH) individual research project grant (R01), and the FIRST (R29) award. Responsibility for the planning, direction, and execution of the proposed project will be solely that of the applicant. The total project period for applications submitted in response to this RFA may not exceed five years. The earliest anticipated award date is September 1994.

This RFA is a one-time solicitation. Future unsolicited competing-continuation applications will compete with investigator-initiated applications and be reviewed according to customary review procedures.

FUNDS AVAILABLE

The estimated minimum total funds (direct and indirect costs) available for the first year of this program will be $1,500,000. In fiscal year 1994, the NIAID plans to fund at least six R01s and/or R29s. This level of support is dependent on the receipt of a sufficient number of applications of high scientific merit.

RESEARCH OBJECTIVES

The goal of this RFA is to stimulate new and innovative programs of basic and preclinical research focused on host immune responses to Lyme disease that will lead to the development of candidate vaccines. Applications submitted in response to this RFA should focus on characterizing protective and pathologic immune responses that will guide the logical development of vaccine candidates for human use. Applications with a primary focus on the development of new animal models are not appropriate for this RFA. A separate solicitation for the development of animal models for vaccine testing is planned. Examples of research goals that are appropriate for pursuing through this RFA, include, but are not limited to:

o The characterization of protective immune responses, including the ontribution of antibodies, cytokines and cell-mediated responses.

o The identification of B- and T-cell epitopes that play a major role in the development of protective immunity and could be considered as likely vaccine candidates.

o The identification and characterization of cross-reacting antigens that may elicit adverse host reactions to immunization.

o The establishment of objective criteria for distinguishing chronic Lyme disease from other disease states.

o Delineation of the role(s) of borrelia antigen variability, molecular mimicry and persistence of bacteria or antigens in chronic Lyme disease.

o The evaluation of candidate immunogens for the duration of active immunity, and the extent of cross-protection among borrelia strains.

o Studies of host-bacterium or host-vector-bacterium interactions important in the establishment or prevention of infection.

These studies are all necessary prerequisites to the development of an effective vaccine that will protect human hosts from infection without risk of harmful side effects resulting from immunization.

SPECIAL REQUIREMENTS

NIAID program staff will organize annual meetings which Principal Investigators, and other key members (as designated by the Principal Investigators in consultation with the program staff) of the projects, will be asked to attend to discuss progress. This will facilitate overall program planning and development, evaluation of the feasibility of planned approaches, and will promote productive interactions among the awardees. Funds for travel to these meetings must be included in the budget. NIAID program staff will also ensure and arrange for the participation in these meetings of investigators from other relevant NIAID-supported Lyme disease research projects, if appropriate, in order to further promote relevant interactions.

STUDY POPULATIONS

SPECIAL INSTRUCTIONS FOR INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDIES

For projects involving clinical research, NIH requires applicants to give special attention to the inclusion of women and minorities in study populations. If women or minorities are not included in the study populations for clinical studies, a specific justification for this exclusion must be provided. Applications without such documentation will not be accepted for review.

LETTER OF INTENT

Prospective applicants are asked to submit, by February 7, 1994, a letter of intent that includes a descriptive title of the proposed research, the name, address and telephone number and FAX number of the Principal Investigator, the identities of other key personnel and the participating institution(s), and the number and title of the RFA in response to which the application may be submitted. A letter of intent is not required, is not binding, and does not enter into the review of subsequent applications. It will be used to assist NIAID staff to estimate the potential review workload and avoid conflict of interest in the review.

The letter of intent is to be sent to Dr. Olivia Preble at the address listed under INQUIRIES.

APPLICATION PROCEDURES

The research grant application form PHS 398 (rev. 9/91) is to be used in applying for these grants. These forms are available at most institutional offices of sponsored research and from the Office of Grants Information, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone 301/594-7248. The deadline for receipt of applications is March 18, 1994. Applicants for FIRST (R29) awards must attach three reference letters (in sealed envelopes) to the face page of the original application. FIRST Award (R29) applications submitted without the required number of reference letters will be considered incomplete and will be returned without review.

Applicants from institutions that have a General Clinical Research Center (GCRC) funded by the NIH National Center of Research Resources may wish to identify the Center as a resource for conducting the proposed research. If so, a letter of agreement from the GCRC Program Director should be included in the application material.

The RFA label available in the PHS 398 (rev. 9/91) application form must be affixed to the bottom of the face page. Failure to use this label could result in delayed processing of the application such that it may not reach the review committee in time for review. In addition, the RFA title (Immune Responses to Lyme Disease Infection and Vaccination) and number (AI-94-008) must be typed on line 2a of the face page of the application.

The typed original, signed application package and three exact single-sided photocopies must be sent or delivered in one package to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

At the time of submission, two additional exact copies must be sent to Dr. Olivia Preble at the address listed under INQUIRIES.

Applications received after the receipt date will be returned without review. The Division of Research Grants (DRG) will not accept any application in response to this announcement that is essentially the same as one currently pending initial review, unless the applicant withdraws the pending application. The DRG will not accept any application that is essentially the same as one already reviewed. This does not exclude the submission of substantial revisions of application already reviewed. These applications must, however, include an introduction addressing the previous critique.

REVIEW CONSIDERATIONS

Upon receipt, applications and supporting material will be reviewed by the DRG for completeness and by the NIAID staff for responsiveness to the RFA. Incomplete and non-response applications will be returned to the applicant without further consideration or review. The NIAID will remove from further competition those applications judged to be non-competitive for award and will notify the applicant and the institutional business official. Those applications judged to be competitive for award will be further reviewed for scientific and technical merit by an appropriate review committee. A second level of review will be provided by the NIAID Council.

Review criteria for applications received in response to an RFA are generally the same as those for unsolicited applications:

o Scientific, technical, or medical significance and originality of the proposed research.

o Appropriateness and adequacy of the experimental approach and methodology proposed to accomplish the research.

o Qualification and research experience of the Principal Investigator and staff, particularly, but nor exclusively, in the area of the proposed research.

o Availability of resources to carry out the proposed research.

o Appropriateness of the proposed budget and duration of the project in relation to the proposed research.

AWARD CRITERIA

The anticipated date of award is September 1994. The NIAID will consider for funding all R01s and R29s rated by peer review as having significant and substantial scientific merit. Awards are subject to the availability of funds. Applications will also be rated for their responsiveness to the aims of the RFA.

INQUIRIES

Written and telephone inquiries concerning this RFA are encouraged. The opportunity to clarify issues or questions from potential applicants is welcome.

Inquiries regarding programmatic issues may be directed to:

Dr. Edward McSweegan
Division of Microbiology and Infectious Diseases
National Institute of Allergy and Infectious Diseases
Solar Building, Room 3A32
6003 Executive Boulevard
Bethesda, MD 20892
Telephone: (301) 496-7728
FAX: (301) 402-2508
E-mail: EM8P@NIH.GOV

Direct inquiries regarding the review of applications to:

Dr. Olivia Preble
Division of Extramural Activities
National Institute of Allergy and Infectious Diseases
Solar Building, Room 4C20
6003 Executive Boulevard
Bethesda, MD 20892
Telephone: (301) 496-8208
FAX: (301) 402-2638

Direct inquiries regarding fiscal matters to:

Mr. Todd Ball
Division of Extramural Activities
National Institute of Allergy and Infectious Diseases
Solar Building, Room 4B35
6003 Executive Boulevard
Bethesda, MD 20892***
Telephone: (301) 496-7075

Schedule

Letter of Intent Receipt Date: February 4, 1994
Application Receipt Date: March 18, 1994
Scientific Review Date: June 15, 1994
Advisory Council Date: September 1994
Earliest Award Date: September 1994

AUTHORITY AND REGULATIONS

This program is supported under authorization of the Public Health Service Act, Sec. 301 (c), Public Law 78-410, as amended. The Catalogue of Federal Domestic Assistance Citation is Sec. 93.856, Microbiology and Infectious Diseases Research. Awards will be administered under PHS grants policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems review.